

REMARKS

Claims 54-63 and 66-99 are pending in this application. Claims 1-53 and 64-65 have been cancelled without prejudice or disclaimer to the subject matter recited therein. Claims 54 and 92 have been amended. Claims 67-91 and 93 have been withdrawn as being directed to non-elected subject matter.

Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 54 has been amended to recite "[a] method for preserving a biological material selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes, the method comprising: (a) adding a preservation solution to said biological material, the preservation solution comprising one or more polyphenols; (b) freeze drying the biological material; and (c) storing the biological material under appropriate storing conditions." Support for the amendment to claim 54 can be found throughout the specification and claims as originally filed.

Claim 92 has been amended to recite "[a] method for preserving a biological material biological material selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes, comprising: (a) adding a preservation solution to the biological material,

the preservation solution comprising one or more polyphenols and being free from any polyalcohol; (b) freeze drying the biological material; and (c) storing the biological material under appropriate storing conditions." Support for the amendment to claim 92 can be found throughout the specification and claims as originally filed.

Claims 94-99 have been newly added. New claims 94-99 recite, for example, that at least 30%, 50% and 75% of the biological material in claims 54 and 92 remains viable.

No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, the Examiner objects to the specification.

The Examiner asserts that the amendment inserting the claim for priority contains new matter because of its incorporation by reference to the content of the two provisional applications.

In view of the remarks set forth herein, this rejection is respectfully traversed.

Applicants respectfully note that the specification has been amended to correct a typographical error. In particular, Applicants submit that the filing date of US Provisional Patent Application No. 60/540,557 has been amended to

reflect February 2, 2004. Accordingly, Applicants submit that the specification does not include new matter.

II. At page 4 of the Official Action, claim 92 have been rejected under 35 USC § 112, second paragraph.

The Examiner asserts that claim 92 is indefinite because the meaning of the phrase "essentially free" is not clear

In view of the remarks set forth herein, this rejection is respectfully traversed.

While Applicants maintain the position set forth in the previous Official Action regarding the Applicable definition of "essentially free" given in the specification, solely in order to expedite allowance of the pending claims Applicants have deleted the term "essentially" from claim 92.

In view of the amendment to claim 92, Applicants submit that claim 92 is clear and definite within the meaning of 35 USC § 112, second paragraph. Therefore, the Examiner is respectfully requested to withdraw this rejection.

III. At page 6 of the Official Action, claims 54-59, 63 and 92 have been rejected under 35 USC § 102(b) as being anticipated by Gen (US Patent Publication No. 2002/0119946).

The Examiner asserts that Gen teaches each and every element of claims 54-59, 63 and 92.

In view of the remarks set forth herein, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that claims 54 and 92 each recite that the biological material is selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes. Claims 55-59 and 63 depend directly from claim 54.

In contrast, Gen is directed to Gen describes the formation of a protein complex with polyphenols, such as catechins for sustained release drug delivery, for introducing genes into cells, etc. The resulting complex may be subjected to freeze drying. See Gen, generally.

However, unlike the presently claimed subject matter, Gen does not teach or suggest a method for preserving a biological material **selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes**, as presently claimed. With regard to the presently claimed biological material, Applicants submit that the present claims no longer recite "biological fluid." Therefore, Gen does not teach each and every element of the claimed subject matter.

In view of the foregoing, that none of the present claims are anticipated by Gen et al. under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this.

IV. At page 4 of the Official Action, claims 54-56, 58-60, 62, 63, 66 and 92 have been rejected under 35 USC § 103(a) as being obvious over Mann et al. (US Patent Application Publication No. 2003/0059338).

The Examiner asserts that it would have been obvious to combine the stabilizers of Mann et al. in the form of solutions with the biological material to be sterilized.

In view of the foregoing, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of

what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success. In addition, the prior art reference or references when properly combined, must teach or suggest all the claim limitations.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a proper case of *prima facie* obviousness has not been established because there is no motivation to modify Mann et al. to arrive at the presently claimed subject matter and Mann et al. is not enabled for anything more than freezing of pertinacious material, such as monoclonal immunoglobulin, hemophiliac clotting factor VIII, thrombin, etc.

Independent claim 54 is directed to a method for preserving a biological material selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes, the method comprising: (a) adding a preservation solution to said biological material, the preservation solution comprising one or more polyphenols; (b) freeze drying the biological material; and (c) storing the biological material under appropriate storing conditions. Claims 55-56, 58-60, 62-63 and 66 all depend, either directly or indirectly, from claim 54.

Claim 92 is directed to a method for preserving a biological material selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes, comprising: (a) adding a preservation solution to the biological material, the preservation solution comprising one or more polyphenols and being free from any polyalcohol; (b) freeze drying the biological material; and (c) storing the biological material under appropriate storing conditions.

Once again, Applicants submit that the presently claimed subject matter recites, for the first time, that the addition of at least one polyphenol to preservation solution increase the viability of the freeze dried cells and maintain their functionally post thawing. Applicants note that the presently claimed subject matter is aimed at preservation of cells or cell containing tissues or organs.

In contrast to the presently claimed subject matter, Mann et al. describe sterilizing biological materials to reduce the level of one or more active biological contaminants or pathogens, such as viruses, yeasts, molds, fungi, prions or

similar agents responsible, alone or in combination, for TSEs and/or single or multicellular parasites. The methods described by Mann et al. use flavonoid/flavonol stabilizers in sterilizing biological materials with irradiation. See Mann et al. at the Abstract.

In addition, Applicants note that there would be no motivation to modify Mann et al. to arrive at the presently claimed subject matter. In this regard, while Mann et al. include cells in its definition of biological material, Mann et al. describe *a method for sterilization by irradiation of the biological material so as to eliminate cellular contaminations*. Thus, Mann et al., in fact, aims at reducing and even eliminating any cellular matter in the material. Therefore, Applicants submit that there is no motivation to modify Mann et al. to use polyphenols for retaining cell viability following cryopreservation because doing so would destroy the principle of operation described in Mann et al.

Further, Applicants submit that *Mann et al. is not enabled for anything more than freezing of pertinacious material, such as monoclonal immunoglobulin, hemophiliac clotting factor VIII, thrombin, etc.* In this regard, Applicants note that Mann et al. only provide examples of freezing pertinacious material, such as monoclonal immunoglobulin, hemophiliac clotting factor VIII, thrombin, etc, which, as known to those of ordinary skill in the art is very different than the presently claimed subject matter.

As indicated above, there is a great difference between freezing a pertinacious material and freezing cells or cells containing tissues and organs. Further, the viability of the biological material is not even discussed by Mann et al.

and, therefore, Applicants submit that high viability could not have been expected when using non-permeating cryoprotectants, such as EGCG. Accordingly, Applicants submit that the presently claimed subject matter is not rendered obvious by Mann et al.

In view of the remarks set forth herein, it is submitted that nothing in any of the applied references, taken alone or together, render the presently claimed subject matter obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

V. ***At page 8 of the Official Action, claims 54-61, 63 have been rejected under 35 USC § 103(a) as being obvious over Anzaghi et al. (WO 03/099040).***

The Examiner asserts that it would have been obvious to combine the stabilizers of Anzaghi et al. in the form of solutions with the biological material to be sterilized.

In view of the foregoing, Applicants respectfully traverse the rejection of claims 54-61 and 63.

A brief discussion of the relevant authority regarding obviousness is set forth above with regard to the previous rejection. The discussion is incorporated herein by reference.

It is submitted that a proper case of *prima facie* obviousness has not been established because Anzaghi et al. do not teach or suggest all the limitations of the claims as required by *In re Wilson*.

As discussed, claim 54 is directed to a method for preserving a biological

material selected from the group consisting of cells, cell aggregates, tissue, organs, natural liposomes and synthetic liposomes. Claims 55-61 and 63 all depend, either directly or indirectly, from claim 54.

In contrast to the presently claimed subject matter, Anzaghi et al. describe a dietary supplement containing all of the natural components of wine, except for the volatile ones, in particular ethanol. The dietary supplement is suitable for oral administration and contains antioxidant complexes present in wine vinasses combined with one or more bioavailability promoters. The wine vinasse is regarded as waste matter containing essential compounds, such as anti-oxidants complexes and other typically small molecular weight compounds. This, however, does not include viable cells. See Anzaghi et al. at the Abstract.

Unlike the presently claimed subject matter Anzaghi et al. do not teach or suggest a method for preserving *a biological material selected from the group consisting of cells, cell aggregates, tissue, organs natural liposomes and synthetic liposomes*, as presently claimed. With regard to the presently claimed biological material, Applicants submit that the present claims no longer recite "biological fluid." Therefore, Applicants submit that Anzaghi et al. do not teach or suggest every element of the presently pending claims.

In view of the remarks set forth herein, it is submitted that nothing in any of the applied references, taken alone or together, renders claims 54-61 and 63 obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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